EXHIBIT C

SUPERIOR COURT OF THE STATE OF CALIFORNIA FOR THE COUNTY OF KERN CASE NO. S-1500-CV 279123 LHB

COLEEN M. PERRY,

PLAINTIFF

vs.

HUNG T. LUU, M.D., JOHNSON & JOHNSON, a New Jersey Corporation; ETHICON, INC., a New Jersey Corporation; and DOES 1-60,

DEFENDANTS

The deposition of SCOTT A. GUELCHER, Ph.D., called by the Defendants for examination, taken before Michelle E. Kerr, RPR, a Notary Public in and for the Commonwealth of Kentucky, Daviess County, at 1719 West End Avenue, Nashville, Tennessee, on December 18, 2014, commencing at 9:40 a.m.

	Page 34		Page 36
1	disclose consulting relationships. When I	1	independent role now as an expert and
2	submit a grant application, I'm required to	2	billing as an expert will have on your
3	disclose whether I have a significant	3	ability to work or run a lab that has
4	financial interest. The NIH changed the	4	federally-funded research?
5	rules in 2012. I disclose whether there is a	5	A Yes, I have.
6	significant financial interest, and then the	6	Q And what affect, if any, have you learned
7	dean's office works with me to figure out if	7	about that?
8	there is a conflict, and if there is, how do	8	A I'm contemplating updating my disclosure.
9	we manage it.	9	And well, I will leave it at that.
10	So there is no fixed set procedure. It's	10	Q Have you had any discussions with anyone at
11	very much handled on a case-by-case basis.	11	Vanderbilt about ways you could work around
12	And disclosures are continuously updated as	12	the ramifications that the receipt of federal
13	new information becomes available.	13	funding has on your role as an expert?
14	Q How is significant financial interest	14	MR. KUNTZ: Objection.
15	defined?	15	A I don't like this word work around. That's
16	A The NIH defines a significant financial	16	not what we do. We identify conflicts. We
17	interest as \$5,000 a year. That's one way to	17	disclose information to the dean's office.
18	define it. Another is equity. Strike that.	18	We work with the dean's office to identify
19	The NIH defines it as \$5,000 or greater.	19	conflicts. If conflicts are identified, we
20	Financial interest, that could be cash. That	20	work with the dean's office and the general
21	could be equity. That could be any form of	21	counsel's office to identify and manage a
22	compensation, but the threshold is \$5,000.	22	plan, which is then approved approved by
23	Q Have all monies you receive in your role as	23	the conflict of interest committee.
24	an expert in the transvaginal mesh litigation	24	I've been through this process multiple
25	for the calendar year 2014 been paid to you	25	times. I've had management plans. I've been
	Page 35		Page 37
1	through Dr. Dunn's company?	1	disclosing conflicts to Vanderbilt since I
2	A The money I have received has all been	2	started there. There is a very standard and
3	received through Dr. Dunn's company, that's	3	routine process. Faculty are allowed and
4	right, yes. The money I received, yes.	4	encouraged to participate in activities
5	Q Does anyone at Vanderbilt know the scope of	5	outside of Vanderbilt. I do this in the
6	Dr. Dunn's company?	6	course of my research with licensing,
7	A I can't speak to Dr. Dunn's company. I don't	7	start-up companies. This is routine.
8	know the details of his arrangement with the	8	There is a process and a procedure. And
9	university. I just don't. He has a	9	we're not working around anything. We're
	1'CC 44 C '4 44 T1	10	
10	different type of appointment than I have.		trying to find a way to work within the
10 11	He doesn't do federally-funded research.	11	trying to find a way to work within the framework of the federal regulations and
	** **	l .	
11	He doesn't do federally-funded research.	11	framework of the federal regulations and
11 12	He doesn't do federally-funded research. That's what I know. I don't know the details	11 12	framework of the federal regulations and university policy. It's very standard for
11 12 13	He doesn't do federally-funded research. That's what I know. I don't know the details of his arrangement with Vanderbilt.	11 12 13	framework of the federal regulations and university policy. It's very standard for universities.
11 12 13 14	He doesn't do federally-funded research. That's what I know. I don't know the details of his arrangement with Vanderbilt. Q Is Dr. Dunn in a position of authority over	11 12 13 14	framework of the federal regulations and university policy. It's very standard for universities. BY MR. SNELL:
11 12 13 14 15	He doesn't do federally-funded research. That's what I know. I don't know the details of his arrangement with Vanderbilt. Q Is Dr. Dunn in a position of authority over you at Vanderbilt?	11 12 13 14 15	framework of the federal regulations and university policy. It's very standard for universities. BY MR. SNELL: Q Have you told Vanderbilt how much money you
11 12 13 14 15	He doesn't do federally-funded research. That's what I know. I don't know the details of his arrangement with Vanderbilt. Q Is Dr. Dunn in a position of authority over you at Vanderbilt? A No.	11 12 13 14 15 16	framework of the federal regulations and university policy. It's very standard for universities. BY MR. SNELL: Q Have you told Vanderbilt how much money you have earned as an expert in the transvaginal
11 12 13 14 15 16	He doesn't do federally-funded research. That's what I know. I don't know the details of his arrangement with Vanderbilt. Q Is Dr. Dunn in a position of authority over you at Vanderbilt? A No. Q If Dr. Dunn wanted to do federally-funded	11 12 13 14 15 16 17	framework of the federal regulations and university policy. It's very standard for universities. BY MR. SNELL: Q Have you told Vanderbilt how much money you have earned as an expert in the transvaginal mesh litigation?
11 12 13 14 15 16 17	He doesn't do federally-funded research. That's what I know. I don't know the details of his arrangement with Vanderbilt. Q Is Dr. Dunn in a position of authority over you at Vanderbilt? A No. Q If Dr. Dunn wanted to do federally-funded research, would he be able to in light of his	11 12 13 14 15 16 17 18	framework of the federal regulations and university policy. It's very standard for universities. BY MR. SNELL: Q Have you told Vanderbilt how much money you have earned as an expert in the transvaginal mesh litigation? A You have asked me this before. And I said we
11 12 13 14 15 16 17 18	He doesn't do federally-funded research. That's what I know. I don't know the details of his arrangement with Vanderbilt. Q Is Dr. Dunn in a position of authority over you at Vanderbilt? A No. Q If Dr. Dunn wanted to do federally-funded research, would he be able to in light of his activities and the amount of money his	11 12 13 14 15 16 17 18	framework of the federal regulations and university policy. It's very standard for universities. BY MR. SNELL: Q Have you told Vanderbilt how much money you have earned as an expert in the transvaginal mesh litigation? A You have asked me this before. And I said we are not required in the course of our work to
11 12 13 14 15 16 17 18 19 20	He doesn't do federally-funded research. That's what I know. I don't know the details of his arrangement with Vanderbilt. Q Is Dr. Dunn in a position of authority over you at Vanderbilt? A No. Q If Dr. Dunn wanted to do federally-funded research, would he be able to in light of his activities and the amount of money his company bills for expert work in the	11 12 13 14 15 16 17 18 19 20	framework of the federal regulations and university policy. It's very standard for universities. BY MR. SNELL: Q Have you told Vanderbilt how much money you have earned as an expert in the transvaginal mesh litigation? A You have asked me this before. And I said we are not required in the course of our work to disclose that. If I believe that I see a
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11 12 13 14 15 16 17 18 19 20 21	He doesn't do federally-funded research. That's what I know. I don't know the details of his arrangement with Vanderbilt. Q Is Dr. Dunn in a position of authority over you at Vanderbilt? A No. Q If Dr. Dunn wanted to do federally-funded research, would he be able to in light of his activities and the amount of money his company bills for expert work in the transvaginal mesh litigation? A I can't speak to that. I don't know how much	11 12 13 14 15 16 17 18 19 20 21 22	framework of the federal regulations and university policy. It's very standard for universities. BY MR. SNELL: Q Have you told Vanderbilt how much money you have earned as an expert in the transvaginal mesh litigation? A You have asked me this before. And I said we are not required in the course of our work to disclose that. If I believe that I see a conflict between my research and the consulting, then I will disclose that and the

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	Page 38		Page 40
1	work.	1	if and when I submit a grant application,
2	Q So the answer to my question is, no, you have	2	that would create the conflict, but that's
3	not disclosed that to Vanderbilt, correct?	3	tied to INH funding. That's not why I'm
4	A I'm not required strike that.	4	not required to disclose it unless there is a
5	Q My question is simple. Have you disclosed to	5	conflict of the federally-funded research
6	Vanderbilt	6	project.
7	A And I believe I have answered your question.	7	Q Have you performed any testing on Ms. Perry's
8	Q I think you are telling me about what you're	8	mesh?
9	required to do.	9	A I have not.
10	I'm asking you, have you, Dr. Guelcher,	10	Q Have you looked at Ms. Perry's mesh under a
11	disclosed to Vanderbilt the monies, the	11	scanning electron microscope?
12	amount of monies you have earned as a	12	A I have not.
13	plaintiff's expert in transvaginal mesh	13	Q What are all of the different tests, methods
14	litigation?	14	that one can do to try to determine whether
15	MR. KUNTZ: Object. Answer it.	15	there is degradation of polypropylene?
16	BY MR. SNELL:	16	A So degradation of polypropylene could be
17	Q It's a yes or no answer.	17	assessed by SEM imaging. That's typically
18	A No, I've not disclosed, but I'm not	18	how we assess it.
19	Q Have you informed your dean of your current	19	Q FTIR
20	intention to bill as an independent	20	A FTIR I'm sorry.
21	consultant to attorneys in the transvaginal	21	Q FTIR is a way that one can go about trying to
22	mesh litigation?	22	assess whether there is degradation of
23	A Why would I inform the dean of this? I've	23	polypropylene, correct?
24	not informed the dean. I have to inform the	24	A No, that's not why we use FTIR. We use FTIR
25	dean when I believe there is a conflict. And	25	· · · · · · · · · · · · · · · · · · ·
23	dean when I believe there is a conflict. And	25	to assess for oxidation, chemical changes in
	Page 39		Page 41
1	if and when I make that assessment, I will	1	Page 41 the polypropylene. That can be assessed by
1 2		1 2	
	if and when I make that assessment, I will	1	the polypropylene. That can be assessed by
2	if and when I make that assessment, I will update my disclosure. But according to	2	the polypropylene. That can be assessed by the FTIR.
2	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do	2 3	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR,
2 3 4	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things.	2 3 4	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there
2 3 4 5	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at	2 3 4 5	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to
2 3 4 5 6	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at \$285 an hour thus far, that is over \$5,000.	2 3 4 5 6	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to degradation; is that correct?
2 3 4 5 6 7	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at \$285 an hour thus far, that is over \$5,000. Are you telling me that if you have a greater	2 3 4 5 6 7	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to degradation; is that correct? A No. We are looking at oxidation to answer
2 3 4 5 6 7 8	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at \$285 an hour thus far, that is over \$5,000. Are you telling me that if you have a greater than \$5,000 interest in your role as an	2 3 4 5 6 7 8	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to degradation; is that correct? A No. We are looking at oxidation to answer the specific question of is the surface
2 3 4 5 6 7 8	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at \$285 an hour thus far, that is over \$5,000. Are you telling me that if you have a greater than \$5,000 interest in your role as an independent billing consultant to	2 3 4 5 6 7 8	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to degradation; is that correct? A No. We are looking at oxidation to answer the specific question of is the surface oxidizing, is it chemically changing. And we
2 3 4 5 6 7 8 9	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at \$285 an hour thus far, that is over \$5,000. Are you telling me that if you have a greater than \$5,000 interest in your role as an independent billing consultant to transvaginal mesh litigation, you do not need	2 3 4 5 6 7 8 9	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to degradation; is that correct? A No. We are looking at oxidation to answer the specific question of is the surface oxidizing, is it chemically changing. And we can see that by peaks in the FTIR spectra
2 3 4 5 6 7 8 9 10	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at \$285 an hour thus far, that is over \$5,000. Are you telling me that if you have a greater than \$5,000 interest in your role as an independent billing consultant to transvaginal mesh litigation, you do not need to tell that to the dean?	2 3 4 5 6 7 8 9 10	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to degradation; is that correct? A No. We are looking at oxidation to answer the specific question of is the surface oxidizing, is it chemically changing. And we can see that by peaks in the FTIR spectra that are not there in the normal
2 3 4 5 6 7 8 9 10 11	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at \$285 an hour thus far, that is over \$5,000. Are you telling me that if you have a greater than \$5,000 interest in your role as an independent billing consultant to transvaginal mesh litigation, you do not need to tell that to the dean? MR. KUNTZ: Objection.	2 3 4 5 6 7 8 9 10 11	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to degradation; is that correct? A No. We are looking at oxidation to answer the specific question of is the surface oxidizing, is it chemically changing. And we can see that by peaks in the FTIR spectra that are not there in the normal polypropylene, but do appear for oxidized
2 3 4 5 6 7 8 9 10 11 12	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at \$285 an hour thus far, that is over \$5,000. Are you telling me that if you have a greater than \$5,000 interest in your role as an independent billing consultant to transvaginal mesh litigation, you do not need to tell that to the dean? MR. KUNTZ: Objection. A No, you are misinterpreting and	2 3 4 5 6 7 8 9 10 11 12 13	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to degradation; is that correct? A No. We are looking at oxidation to answer the specific question of is the surface oxidizing, is it chemically changing. And we can see that by peaks in the FTIR spectra that are not there in the normal polypropylene, but do appear for oxidized polypropylene.
2 3 4 5 6 7 8 9 10 11 12 13 14	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at \$285 an hour thus far, that is over \$5,000. Are you telling me that if you have a greater than \$5,000 interest in your role as an independent billing consultant to transvaginal mesh litigation, you do not need to tell that to the dean? MR. KUNTZ: Objection. A No, you are misinterpreting and misunderstanding what I have said. The	2 3 4 5 6 7 8 9 10 11 12 13	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to degradation; is that correct? A No. We are looking at oxidation to answer the specific question of is the surface oxidizing, is it chemically changing. And we can see that by peaks in the FTIR spectra that are not there in the normal polypropylene, but do appear for oxidized polypropylene. Q Now, as I understand it, Dr. Dunn, in prior
2 3 4 5 6 7 8 9 10 11 12 13 14 15	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at \$285 an hour thus far, that is over \$5,000. Are you telling me that if you have a greater than \$5,000 interest in your role as an independent billing consultant to transvaginal mesh litigation, you do not need to tell that to the dean? MR. KUNTZ: Objection. A No, you are misinterpreting and misunderstanding what I have said. The question is, whether the proposed research,	2 3 4 5 6 7 8 9 10 11 12 13 14 15	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to degradation; is that correct? A No. We are looking at oxidation to answer the specific question of is the surface oxidizing, is it chemically changing. And we can see that by peaks in the FTIR spectra that are not there in the normal polypropylene, but do appear for oxidized polypropylene. Q Now, as I understand it, Dr. Dunn, in prior work did FTIR in connection with assessing
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at \$285 an hour thus far, that is over \$5,000. Are you telling me that if you have a greater than \$5,000 interest in your role as an independent billing consultant to transvaginal mesh litigation, you do not need to tell that to the dean? MR. KUNTZ: Objection. A No, you are misinterpreting and misunderstanding what I have said. The question is, whether the proposed research, when I submit a grant application, I submit	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to degradation; is that correct? A No. We are looking at oxidation to answer the specific question of is the surface oxidizing, is it chemically changing. And we can see that by peaks in the FTIR spectra that are not there in the normal polypropylene, but do appear for oxidized polypropylene. Q Now, as I understand it, Dr. Dunn, in prior work did FTIR in connection with assessing the question of is there degradation of
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at \$285 an hour thus far, that is over \$5,000. Are you telling me that if you have a greater than \$5,000 interest in your role as an independent billing consultant to transvaginal mesh litigation, you do not need to tell that to the dean? MR. KUNTZ: Objection. A No, you are misinterpreting and misunderstanding what I have said. The question is, whether the proposed research, when I submit a grant application, I submit an application to the NIH for federal	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to degradation; is that correct? A No. We are looking at oxidation to answer the specific question of is the surface oxidizing, is it chemically changing. And we can see that by peaks in the FTIR spectra that are not there in the normal polypropylene, but do appear for oxidized polypropylene. Q Now, as I understand it, Dr. Dunn, in prior work did FTIR in connection with assessing the question of is there degradation of polypropylene?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at \$285 an hour thus far, that is over \$5,000. Are you telling me that if you have a greater than \$5,000 interest in your role as an independent billing consultant to transvaginal mesh litigation, you do not need to tell that to the dean? MR. KUNTZ: Objection. A No, you are misinterpreting and misunderstanding what I have said. The question is, whether the proposed research, when I submit a grant application, I submit an application to the NIH for federal funding. I have to answer the question, do	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to degradation; is that correct? A No. We are looking at oxidation to answer the specific question of is the surface oxidizing, is it chemically changing. And we can see that by peaks in the FTIR spectra that are not there in the normal polypropylene, but do appear for oxidized polypropylene. Q Now, as I understand it, Dr. Dunn, in prior work did FTIR in connection with assessing the question of is there degradation of polypropylene? A And why is that I don't know what you're
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at \$285 an hour thus far, that is over \$5,000. Are you telling me that if you have a greater than \$5,000 interest in your role as an independent billing consultant to transvaginal mesh litigation, you do not need to tell that to the dean? MR. KUNTZ: Objection. A No, you are misinterpreting and misunderstanding what I have said. The question is, whether the proposed research, when I submit a grant application, I submit an application to the NIH for federal funding. I have to answer the question, do you have a significant financial interest in	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to degradation; is that correct? A No. We are looking at oxidation to answer the specific question of is the surface oxidizing, is it chemically changing. And we can see that by peaks in the FTIR spectra that are not there in the normal polypropylene, but do appear for oxidized polypropylene. Q Now, as I understand it, Dr. Dunn, in prior work did FTIR in connection with assessing the question of is there degradation of polypropylene? A And why is that I don't know what you're referring to.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at \$285 an hour thus far, that is over \$5,000. Are you telling me that if you have a greater than \$5,000 interest in your role as an independent billing consultant to transvaginal mesh litigation, you do not need to tell that to the dean? MR. KUNTZ: Objection. A No, you are misinterpreting and misunderstanding what I have said. The question is, whether the proposed research, when I submit a grant application, I submit an application to the NIH for federal funding. I have to answer the question, do you have a significant financial interest in the outcome of this federally-funded project.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to degradation; is that correct? A No. We are looking at oxidation to answer the specific question of is the surface oxidizing, is it chemically changing. And we can see that by peaks in the FTIR spectra that are not there in the normal polypropylene, but do appear for oxidized polypropylene. Q Now, as I understand it, Dr. Dunn, in prior work did FTIR in connection with assessing the question of is there degradation of polypropylene? A And why is that I don't know what you're referring to. Q I recall in your Huskey testimony, in your
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at \$285 an hour thus far, that is over \$5,000. Are you telling me that if you have a greater than \$5,000 interest in your role as an independent billing consultant to transvaginal mesh litigation, you do not need to tell that to the dean? MR. KUNTZ: Objection. A No, you are misinterpreting and misunderstanding what I have said. The question is, whether the proposed research, when I submit a grant application, I submit an application to the NIH for federal funding. I have to answer the question, do you have a significant financial interest in the outcome of this federally-funded project. Significant financial interest is defined	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to degradation; is that correct? A No. We are looking at oxidation to answer the specific question of is the surface oxidizing, is it chemically changing. And we can see that by peaks in the FTIR spectra that are not there in the normal polypropylene, but do appear for oxidized polypropylene. Q Now, as I understand it, Dr. Dunn, in prior work did FTIR in connection with assessing the question of is there degradation of polypropylene? A And why is that I don't know what you're referring to. Q I recall in your Huskey testimony, in your deposition, you testified that all of the
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at \$285 an hour thus far, that is over \$5,000. Are you telling me that if you have a greater than \$5,000 interest in your role as an independent billing consultant to transvaginal mesh litigation, you do not need to tell that to the dean? MR. KUNTZ: Objection. A No, you are misinterpreting and misunderstanding what I have said. The question is, whether the proposed research, when I submit a grant application, I submit an application to the NIH for federal funding. I have to answer the question, do you have a significant financial interest in the outcome of this federally-funded project. Significant financial interest is defined as more than \$5,000. But at this point in	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to degradation; is that correct? A No. We are looking at oxidation to answer the specific question of is the surface oxidizing, is it chemically changing. And we can see that by peaks in the FTIR spectra that are not there in the normal polypropylene, but do appear for oxidized polypropylene. Q Now, as I understand it, Dr. Dunn, in prior work did FTIR in connection with assessing the question of is there degradation of polypropylene? A And why is that I don't know what you're referring to. Q I recall in your Huskey testimony, in your deposition, you testified that all of the testing done was done by Dr. Dunn. And I
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	Page 42		Page 44
1	did for the Huskey trial. I do believe we	1	BY MR. SNELL:
2	did FTIR. I don't remember the others, but	2	Q The fact that's it's a strong indicator,
3	oxidation and degradation are related, but	3	though, that in and of itself means that
4	they're in terms of and there may be	4	there is some possibility that you will not
5	times that people use the word degradation to	5	see physical degradation, and there is a
6	consider all of these effects, but I'm	6	possibility as well that you will see it,
7	speaking specifically about oxidation as a	7	physical degradation, if you look at SEM,
8	chemical process, and degradation as a	8	correct?
9	physical one, and they're assessed by	9	MR. KUNTZ: Objection.
10	different techniques.	10	A Again, the literature tells us that you would
11	And I don't remember all of the testing	11	expect degradation. Is it unless you
12	that Dr. Dunn did for the Huskey trial. I	12	actually see it, you can't prove you can't
13	don't remember that.	13	guarantee that it's there, but you would
14	Q So if one does FTIR testing and sees that the	14	certainly expect it. It's within a
15	surface is oxidized, that does not	15	reasonable degree of scientific certainty to
16	necessarily mean that the material is	16	expect that you would have degradation in
17	degraded, correct?	17	time if that surface is being oxidized.
18	A There are different tests to assess they	18	There are numerous papers that teach
19	could be degraded, but we would assess	19	about this, about polymers in general,
20	degradation using a different technique than	20	polymers that are susceptible to oxidative
21	FTIR. FTIR, as I said, is for chemical	21	attack showed signs of physical degradation.
22	oxidation, which is a chemical change. There	22	This was all worked out a number of years
23	may be degradation, but we would confirm that	23	ago.
24	with a technique such as SEM.	24	MR. SNELL: Move to strike.
25	Q So if a scientist has a positive FTIR finding	25	BY MR. SNELL:
	1 2		
	Page 43		Page 45
1	for oxidation on the surface, he would then	1	Q My question is this. It's straight forward.
2	need to confirm that with SEM in order to	2	The fact that you see chemical oxidation,
3			The fact that you see chemical oxidation,
J	reasonably say with scientific certainty that	3	that does not mean that you would also see
4	reasonably say with scientific certainty that there was degradation?		that does not mean that you would also see under SEM analysis physical degradation if
	reasonably say with scientific certainty that there was degradation? MR. KUNTZ: Objection.	3	that does not mean that you would also see
4	reasonably say with scientific certainty that there was degradation?	3 4	that does not mean that you would also see under SEM analysis physical degradation if
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	Page 46		Page 48
1	the implications will be.	1	time periods of three months and later.
2	Q Do you have an opinion as to what is the	2	That's what Clave reported.
3	earliest point in time where there can be	3	Q And you have a list of materials here today.
4	physical degradation of Ethicon's Prolene	4	Where in Clave does it say that
5	polypropylene used in TVT Abbrevo?	5	A I would have to see the paper. I know that
6	A Again, that's a speculative question. I	6	in Clave, it says that he notes that
7	believe that upon implantation, the device	7	explants I would have to see it to give a
8	will be colonized by adherent inflammatory	8	precise answer. The number I remember is
9	cells. This is well-known in the literature,	9	three months.
10	the foreign body reaction. Those cells will	10	(Deposition Exhibit No. 1 was
11	secrete species that oxidize it. The timing	11	marked for identification.)
12	of all these events can depend on a number of	12	BY MR. SNELL:
13	factors, the nature of the inflammatory	13	Q Doctor, I've handed you Exhibit No. 1. Is
14	response where it's implanted, the mechanical	14	that the Clave paper you were referring to,
15	stresses in the environment, whether there is	15	sir?
16	a bacterial infection.	16	A That is correct.
17	The timing can be highly variable. It	17	Q So can you show me where in Clave it states
18	can happen early or it can happen late. The	18	that physical degradation occurred in the
19	point is that it's unpredictable. That's	19	Prolene polypropylene mesh at a certain time
20	what I've been saying.	20	period?
21	Q Well, I would like to know what does the	21	A I'm looking for that. So on Page 264 of
22	literature teach you about the earliest point	22	Clave, it states degradation was observed
23	in time when you can say there is physical	23	only in samples implanted for at least three
24	degradation of the Prolene polypropylene	24	months.
25	mesh?	25	Q That is a general statement about the overall
	Page 47		Page 49
1	I don't want to rehash everything you	1	cohort of explants, correct?
2	talked about in Huskey. I know you talked	2	A That's my understanding.
3	about what was seen in two years and I	3	Q That statement is not necessarily particular
4	believe five or seven years in a dog study	4	to a Prolene polypropylene mesh implant,
5	and things like that. So with all of those	5	correct?
6	principles that you've already testified	6	
7			A There could have been Prolene implants in
/	about, let me just back up and re-ask it.	7	A There could have been Prolene implants in this study. That statement doesn't specify
	about, let me just back up and re-ask it. A Okay.	7	this study. That statement doesn't specify
8	A Okay.	7 8	this study. That statement doesn't specify whether that applies to Prolene or not.
	A Okay. MR. KUNTZ: Objection.	7	this study. That statement doesn't specify whether that applies to Prolene or not. Q So my question is, can you point to any
8 9	A Okay. MR. KUNTZ: Objection. BY MR. SNELL:	7 8 9	this study. That statement doesn't specify whether that applies to Prolene or not. Q So my question is, can you point to any literature which informs you of the earliest
8 9 10	A Okay. MR. KUNTZ: Objection. BY MR. SNELL: Q What is the earliest point in time that you	7 8 9 10 11	this study. That statement doesn't specify whether that applies to Prolene or not. Q So my question is, can you point to any literature which informs you of the earliest time which the Prolene polypropylene mesh
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8 9 10 11 12 13 14 15 16 17 18 19 20 21	A Okay. MR. KUNTZ: Objection. BY MR. SNELL: Q What is the earliest point in time that you can say that there is physical degradation of the Prolene polypropylene mesh? A I just can't answer that question. There are too many factors that can influence it. To say again, it's too speculative. It depends on many factors in addition to the chemical oxidation. Q Based on all of the literature that you saw, what was the earliest time reported that there was physical degradation of the Prolene polypropylene mesh?	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	this study. That statement doesn't specify whether that applies to Prolene or not. Q So my question is, can you point to any literature which informs you of the earliest time which the Prolene polypropylene mesh physically degrades? MR. KUNTZ: Objection. A I don't know of this you mean in vivo of patients? BY MR. SNELL: Q Yes, sir. A I don't know of a study that has specifically reported that. Q In the dog study and you're still relying on the dog study as well with the Prolene sutures?

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	Page 50		Page 52
1	Q At what point in time was physical	1	BY MR. SNELL:
2	degradation observed in that study?	2	Q My question was not what is he saying. My
3	A I can't remember. I would have to look at	3	question was to you, what limitations does
4	the document.	4	that place upon what one can draw from Clave
5	Q Okay. At a break, I would like for you to	5	due to the fact that only 32 out of 100
6	look at that document. And I will have the	6	explants were submitted for chemical testing?
7	same question for the vascular graft Prolene	7	A I don't see how it limits the finding that he
8	suture study, what is the earliest point in	8	sees changes. That's what he is reporting,
9	that study if at any point in time it showed	9	whether he sees it in 32 or 50, whether he
10	physical degradation?	10	looked at 32 or 100. I mean, you may be
11	A Again, I would have to look at it. I don't	11	implying that he was cherry-picking data, but
12	remember that level of detail.	12	I have no reason to believe that. This is a
13	Q Am I correct that although Clave reports	13	peer-reviewed journal.
14	there were 100 explanted samples, a smaller	14	I mean, he studied what he could study,
15	number were actually analyzed?	15	but it doesn't limit the finding that these
16	A What do you mean analyzed? I'm not sure what	16	changes happened. Whether he did 32 or 100,
17	you mean.	17	he still saw changes. So I don't understand
18	Q Let me ask you, how many explants were	18	how that limits that finding.
19	analyzed in the Clave study?	19	Q Well, he had 100 explants, and he only
20	A I would have to look at it. There were 100	20	subjected 32 to chemical analysis. We can
21	explants. I'm still not sure what you're	21	agree to that, right?
22	asking, though. I mean, there were 100	22	A That's what he states. But beyond that, I
23	explants.	23	don't
24	Q How many of those 100 explants were actually	24	Q And you don't know the methodology by which
25	analyzed?	25	he selected the particular 32 for chemical
	Page 51		Page 53
1			rage 33
1	A Well, I think it depends on the method, so		1 ' 49
	-	1	analysis, correct?
2	they did a chemical analysis on 32 explants.	2	A Well, let me read it. I need to read this,
3	they did a chemical analysis on 32 explants. It doesn't necessarily say in the methods.	2 3	A Well, let me read it. I need to read this, because I'm not quite following where you are
3 4	they did a chemical analysis on 32 explants. It doesn't necessarily say in the methods. Q Why did Clave do less than one-third of the	2 3 4	A Well, let me read it. I need to read this, because I'm not quite following where you are going with this.
3 4 5	they did a chemical analysis on 32 explants. It doesn't necessarily say in the methods. Q Why did Clave do less than one-third of the overall sample size for chemical analysis?	2 3 4 5	A Well, let me read it. I need to read this, because I'm not quite following where you are going with this. Okay. So he says I mean, he explains
3 4 5 6	they did a chemical analysis on 32 explants. It doesn't necessarily say in the methods. Q Why did Clave do less than one-third of the overall sample size for chemical analysis? A I don't know. I would have to look at this	2 3 4 5 6	A Well, let me read it. I need to read this, because I'm not quite following where you are going with this. Okay. So he says I mean, he explains himself. The samples were divided into four
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1	studies or documents or data that you can	1	of the response, part of the answer.
2	review independently of Dr. Dunn, correct?	2	I'm done. Thank you.
3	A Yes, that's correct.	3	(Deposition was adjourned at 5:50
4	MR. SNELL: Objection. You've	4	p.m.)
5	got to give me a chance to object. Leading,	5	* * *
6	compound. Go ahead.	6	
7	BY MR. KUNTZ:	7	
8	Q You repeatedly in your practice are going to	8	
9	have expertise reviewing those types of	9	
10	studies, SEM, FTIR, and XPS?	10	
11	MR. SNELL: Objection. Leading	11	
12	compound. Go ahead.	12	
13	A Yes, I do.	13	
14	Q And if Ethicon did those studies or had those	14	
15	types of documents, you could review those	15	
16	independently, correct?	16	
17	MR. SNELL: Same objections.	17	
18	A Yes, I could.	18	
19	Q The last question I have. Is there any	19	
20	peer-reviewed article that you're aware of	20	
21	that shows or supports the notion that	21	
22	macrophages in foreign body giant cells can	22	
23	be deactivated?	23	
24	A I'm not aware of such an article.	24	
25	MR. KUNTZ: Okay. No more	25	
	5.065		2 060
	Page 267		Page 269
1	questions.	1	STATE OF KENTUCKY)
2	REDIRECT EXAMINATION	3	COUNTY OF DAVIESS)
3	BY MR. SNELL:	4	COUNTY OF DAVIESS)
4	Q Are you aware of any book chapters, any	5	I, MICHELLE E. KERR, A NOTARY PUBLIC AT LARGE IN
5	articles in the peer-reviewed literature that	6	AND FOR THE COMMONWEALTH OF KENTUCKY, DO HEREBY
6	says that macrophages can indeed be		
7		7	CERTIFY:
	deactivated?	8	THAT SAID DEPOSITION WAS TAKEN STENOGRAPHICALLY
8	A I'm not aware of those articles. That's what	8	THAT SAID DEPOSITION WAS TAKEN STENOGRAPHICALLY AND ELECTRONICALLY BY ME AND THAT THE TYPEWRITTEN
8 9	A I'm not aware of those articles. That's what I said earlier.	8 9 10	THAT SAID DEPOSITION WAS TAKEN STENOGRAPHICALLY AND ELECTRONICALLY BY ME AND THAT THE TYPEWRITTEN TRANSCRIPT ABOVE IS A TRUE RECORD OF THE
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